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9 Attorneys for Plaintiff
10 UNITED STATES OF AMERICA

11 UNITED STATES DISTRICT COURT
12 FOR THE CENTRAL DISTRICT OF CALIFORNIA
13 EASTERN DIVISION
14

15 UNITED STATES OF AMERICA,
16 Plaintiff,
17 v.
18

19 CALIFORNIA STEM CELL
TREATMENT CENTER, INC.,
20 *et al.*

21 Defendants.
22
23

No. 5:18-CV-01005-JBG-KKx

Hon. Jesus G. Bernal
Riverside, Courtroom 1

**DECLARATION OF CHRISTOPHER C.
JONECKIS**

Hearing Date: August 5, 2019
Trial Date: October 1, 2019

24 I, Christopher C. Joneckis, Ph.D., declare the following:
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26 1. I am the Associate Director for Review Management in the Office of the
27 Center Director, Center for Biologics Evaluation and Research, United States Food and
28 Drug Administration ("FDA").


1 2. The existence of a Biologics License Application (“BLA”), New Drug
2 Application (“NDA”), Investigational New Drug Application (“IND”), Premarketing
3 Application (“PMA”), Investigational Drug Exemption (“IDE”), or 510(k) application
4 (“510k”) is reflected in various official FDA records to which I have access, or have
5 requested others to access, as part of my official duties. FDA regularly tracks and
6 maintains these records at or near the time of their submission, communication, or
7 review in the normal course of regulatory affairs, and relies on these records to conduct
8 official business.

9 3. On June 12, 2019, June 25, 2019, and July 1, 2019, I caused a diligent
10 search of the official FDA records referred to in paragraph 2. These searches were
11 conducted using the following search terms: California Stem Cell Treatment Center,
12 Cell Surgical Network, Mark Berman, Elliot Lander, Cells on Ice. The searches also
13 sought information about any BLA, NDA, IND, PMA, IDE or 510k, the subject of
14 which is stromal vascular fraction (SVF); SVF combined with ACAM2000 or Vaccinia
15 Vaccine, Live; and SVF expanded by American CryoStem Corporation in Monmouth
16 Junction, New Jersey.

17 4. The searches described in paragraph 3, revealed that there is no approved
18 BLA, NDA, PMA, or IDE, no IND in effect, and no cleared 510k on file for California
19 Stem Cell Treatment Center, Cell Surgical Network, Mark Berman, Elliot Lander, or
20 Cells on Ice. The searches described in paragraph 3 identified a number of IND and IDE
21 submissions; however, none of those INDs or IDEs are in effect or approved,
22 respectively. As such, there is no approved BLA, NDA, PMA, or IDE, no IND in effect,
23 and no cleared 510(k) on file for California Stem Cell Treatment Center, Cell Surgical
24 Network, Mark Berman, Elliot Lander, or Cells on Ice in connection with SVF; SVF
25 combined with ACAM2000 or Vaccinia Vaccine, Live; and/or SVF expanded by
26 American CryoStem Corporation in Monmouth Junction, New Jersey.

1 Pursuant to 28 U.S.C. § 1746, I declare, under penalty of perjury, the foregoing is
2 true and correct.

3 Executed on July 2, 2019.
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11 Christopher C. Joneckis, Ph.D.
12 Associate Director for Review Management
13 Office of the Center Director
14 Center for Biologics Evaluation and
15 Research
16 U.S. Food and Drug Administration
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